

REMARKS

Claims 1-3 and 5-54 were pending in the instant application. Claims 6-17 and 19-54 were withdrawn by the Examiner as being directed to non-elected subject matter. By this Amendment, the specification has been amended to include sequence identifiers in the legends of Figures 5 and 6 and to indicate renumbering of incorrectly identified sequences. Claim 1 has been amended to replace the term "comprising" with "consisting essentially of" and to provide definitions for "peptide derivative" and "specificity." Support for the amendments to claim 1 can be found, *inter alia*, at pages 9-13 of the specification. New claims 55-59 have been added. Support for new claims 55-56 can be found, *inter alia*, in the specification at page 9, second full paragraph. Support for new claim 57 can be found at pages 9-13 and in originally filed claim 1. Support for new claims 58-59 can be found at page 11, final paragraph. Applicants assert that neither the amendments nor the new claims introduce any new matter, and thus, their entry is requested. Upon entry of the present Amendment, claims 1, 3, 5, 18, and 55-59 will be pending and under examination.

Additionally, attached to this Amendment is a substitute Sequence Listing to address the Examiner's objection. Entry of the substitute Sequence Listing into the application is respectfully requested. A substitute computer-readable form of the Sequence Listing is also submitted, and it is hereby stated that the content of the Sequence Listing information recorded in the computer readable form is identical to the Sequence Listing written on paper and contains no new matter.

Examiner's Acknowledgment of Applicants' Election with Traverse

The Examiner acknowledged Applicants' election with traverse of previously set forth Group VII, claims 1-3, 5, and 18. The Examiner made the restriction requirement final, stating his position that "Applicant's recitation of the open terms 'comprising' and 'peptide derivatives' in claim 1 opens the claim to encompass peptides including those of the Tobin reference. Further, it is the Examiner's position that by demonstrating that a claimed peptide was taught by the prior art, the Examiner has established that no unity of invention exists, thus, restriction is proper."

In light of the amendments to claim 1 presented herein, which overcome the Examiner's concerns as stated above, Applicants respectfully request that the Examiner reconsider and withdraw the previously set forth restriction requirement.

Notice to Comply with Sequence Requirements

The Examiner stated that the sequences of Figure 6 are insufficiently identified by SEQ ID NO.

In response, Applicants have amended the specification to more clearly identify the sequences set forth in the figures and have provided a substitute sequence listing. The substitute sequence listing includes the following corrections to the Sequence listing previously submitted. Previous sequences identified as SEQ ID NOS: 42-45 have been deleted, because they are in fact portions of previously identified SEQ ID

NOS: 38-41. Therefore, previously identified SEQ ID NOS: 46 and 47 have been renumbered as SEQ ID NOS: 42 and 43. SEQ ID NOS: 34-41 have been corrected. In the previously submitted sequence listing, these sequences did not properly include the TCRAV or N-Region portions of the continuous molecule, but rather incorrectly identified each portion as a separate sequence. Support for these amendments can be found at page 39, fifth full paragraph.

Withdrawal of Previous Rejections

Applicants acknowledge and appreciate the Examiner's withdrawal of the previously set forth rejections under 35 U.S.C. § 112, first and second paragraphs.

Rejection under 35 U.S.C. § 102 (b)

The Examiner rejected claims 1-3, 5, and 18 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 95/07992 (of record), for the reasons of record set forth in Paper No. 14, mailed 3/28/01. The Examiner stated that he considered the Applicants' arguments set forth in the Amendment filed September 27, 2001 but was not persuaded. The Examiner asserted that the use of the open language "comprising" in claim 1 encompasses peptides disclosed in the cited reference, despite Applicants' arguments to the contrary.

In response, without conceding the correctness of the Examiner's position, but to advance prosecution of the present application, Applicants have amended claim 1 by

replacing "comprising" with "consisting essentially of." Applicants believe this amendment to the claim obviates the Examiner's rejection under 35 U.S.C. 102 (b). Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Rejection under 35 U.S.C. § 102 (e)

The Examiner rejected claims 1-3, 5, and 18 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,011,139 (of record), for the reasons of record set forth in Paper No. 14, mailed 3/28/01. The Examiner stated that he considered the Applicants' arguments set forth in the Amendment filed September 27, 2001 but was not persuaded. The Examiner, moreover, stated his position that "given the lack of a specific definition of a 'peptide derivative' SEQ ID NO: 50 of the '139 patent, which differs from the claimed peptide by the addition of 2 amino acids at the N-terminus and the deletion of an amino acid at the C-terminus, comprises a 'peptide derivative' of SEQ ID NO: 7." The Examiner further asserted that the Applicant has not sufficiently demonstrated that the peptide of the prior art would not comprise an amino acid sequence having an equivalent specificity as the amino acid sequences recited in (g) of claim 1.

In response, without conceding the correctness of the Examiner's position, but to advance prosecution of the subject application, Applicants have amended claim 1 as indicated above. Applicants also have included within the claim a definition of "peptide

derivative.” Applicants believe that the amendments to claim 1 obviates the Examiner’s rejection under 35 U.S.C. 102 (e). Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Rejection under 35 U.S.C. § 103 (a)

The Examiner rejected claims 1-3, 5, and 18 under 35 U.S.C. § 103(a) as allegedly being obvious over WO 95/07992 (of record) or U.S. Patent No. 6,011,139, Tobin (of record), each in view of U.S. Patent No. 5,750,114, Burke et al. (of record), for the reasons set forth in Paper No. 14, mailed 3/28/01. Specifically, the Examiner relies on Burke for disclosing an HSV polypeptide vaccine comprising immunomodulating cytokines and a pharmaceutically acceptable carrier. The Examiner takes the position that it would have been obvious to have formulated antigenic or immunogenic peptides such as those taught by WO 95/07992 or Tobin into the pharmaceutical composition in Burke to arrive at the Applicants’ claimed pharmaceutical composition of claim 18.

In response, Applicants direct the Examiner’s attention to the remarks set forth above with respect to the teachings of WO 95/07992 and U.S. Patent No. 6,011,139, (Tobin) as well as to the amendments to claim 1 presented herein. Applicants assert that in light of the amendments to claim 1, the cited references as combined by the Examiner fail to teach or suggest the claimed invention as set forth in the claims as amended. Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 103 (a).

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1-3, 5, and 18 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner noted that claim 1 omits a period at the end. The Examiner also asserted that the recitations of “peptide derivative” and “equivalent specificity” are vague because they are not defined.

In response, without conceding the correctness of the Examiner’s position, but to advance prosecution of the instant application, Applicants have included, within the claims, definitions for “peptide derivative” and “specificity.” Applicants have also inserted a period at the end of claim 1. Applicants believe that these claim amendments obviate the Examiner’s rejection under 35 U.S.C. § 112, second paragraph, and respectfully request that the Examiner reconsider and withdraw the rejection.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-3, 5, and 18 under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description. Specifically, the Examiner asserted that the specification and claims as filed do not provide support for the phrase “comprises a C-terminal isoleucine residue” or the reference to “human” MHC molecules, as recited in claim 1.

In response, Applicants respectfully traverse the Examiner’s rejection. Applicants direct the Examiner’s attention to the specification, at page 6, lines 11-20, addressing the importance of the C-terminal isoleucine residue recited in claim 1. With

respect to "human MHC molecules," Applicants direct the Examiner's attention to the data presented in Figures 3A and 4A, demonstrating the results from peptide binding assays for the claimed peptides using the R.B., M.C., and 24/31 T cell lines. Example 2 and Table 1 in the specification specifically describe the experiments that were performed to analyze the subtypes of human MHC molecules to which the claimed peptides bind. Table 1 also lists the R.B. and M.C. T cell lines. These disclosed cell lines are human in origin. Furthermore, Applicants point out that the designations "DR" and "DQ", as recited in the amended claims, describe human MHC molecules.

In light of the above, therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

In view of the above remarks and amendments, Applicants believe that the Examiner's rejections set forth in the October 1, 2002 Office Action have been

overcome and that the present application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,



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Attachments:

Computer and Paper Copies of the substitute Sequence Listing
Marked Up Copies of amendments

2923-393.am1

Marked up Copy of amended Specification Paragraphs

First two full paragraphs at page 29

FIG. 5 shows the result of sequencing TCR .alpha. chains from clones of the T cell lines 40/2 (SEQ ID NOs:34, 35) and 24/31 (SEQ ID NOs:36,37). [Fig.5 also shows nucleotide or amino acid sequences represented by SEQ ID NO: 34,35,36 or 37.]

FIG. 6 shows the result of sequencing TCR β chains from clones of the T cell lines 40/2 (SEQ ID NOs:38,39) and 24/31 (SEQ ID NOs:40,41). [Fig 6 also shows the nucleotide or amino acid sequences represented by SEQ ID NO: 38-45.]

Paragraph bridging pages 37-38

cDNA was synthesized from the RNA by reverse transcription. For this ca. 3 μ g total RNA was incubated for 10 min at 55°C with 30 ng p-C α ST (a specific primer for the TCR α chain having the sequence 5'-CAC TGA AGA TCC ATC ATC TG-3') (SEQ ID NO: 42[46]) and 30 ng p-C β ST (a specific primer for the β chain having the sequence 5'-TAG AGG ATG GTG GCA GAC AG-3') (SEQ ID NO: 43[47]) in a reaction volume of 10 μ l. Subsequently 38 μ l RAV-2-RT buffer (100 mM Tris-HCl pH 8.3; 140 mM KCl, 10 mM MgCl₂; 2 mM dithiothreitol, 0.1 mM of each dNTP), 1 μ l (0.75 U) rRNasin and 1 μ l (18 U) reverse transcriptase were added by pipette. The reverse transcription was carried out for 90 min. at 42°C. followed by a denaturation step at 68°C. for 5 min. It was stored at -80°C. until use.

Marked up Copy of Amended Claim 1

1. (Seven times Amended) Peptide or peptide derivative [comprising] consisting essentially of:

(a) the amino acid sequence (SEQ ID NO:1)

D-V-N-Y-A-F-L-H-A-T-D-L-L-P-A-C-D-G-E-R,

(b) the amino acid sequence (SEQ ID NO:2)

S-N-M-Y-A-M-M-I-A-R-F-K-M-F-P-E-V-K-E-K,

(c) the amino acid sequence (SEQ ID NO:3)

N-W-E-L-A-D-Q-P-Q-N-L-E-E-I-L-M-H-C-Q-T,

(d) the amino acid sequence (SEQ ID NO:4)

T-L-K-Y-A-I-K-T-G-H-P-R-Y-F-N-Q-L-S-T-G,

(e) the amino acid sequence (SEQ ID NO:5)

P-R-Y-F-N-Q-L-S-T-G-L-D-M-V-G-L-A-A-D-W,

(f) the amino acid sequence (SEQ ID NO:6)

T-Y-E-I-A-P-V-F-V-L-L-E-Y-V-T-L-K-K-M-R,

(g) the amino acid sequence (SEQ ID NO:7)

F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I, wherein the peptide or peptide derivative of SEQ ID [NO.]NO: 7 comprises a C-terminal isoleucine residue,

(h) a partial region of the amino acid sequence shown in (a), (b), (c), (d), (e), (f) or (g) with a length of at least 6 amino acids, or

- (i) an amino acid sequence which has [an equivalent specificity or] a binding specificity or affinity to human MHC molecules [as] equivalent to the amino acid sequence shown in (a), (b), (c), (d), (e), (f), (g) or (h);

wherein said peptide or peptide derivative has a length of up to 25 amino acids, wherein the peptide derivative is a peptide derivatized by a chemical reaction or in which at least one amino acid has been replaced by a naturally occurring or non-naturally occurring amino acid homologue, and wherein specificity indicates a capability of recognizing DR-type MHC class II molecules.